

MAY 13 2005



## 510(k) Summary<sup>1</sup>

(a) (1) **Submitter's name, address**

Bionostics, Inc.  
7 Jackson Road  
Devens, MA 01434

**Contact Person**

Kathleen Storro  
Sr. Director, QA & Regulatory Affairs  
(978) 772-7070 x 220

**Date of preparation of this summary:** 15 April 2005

(2) **Device trade or proprietary name:** **RNA1c** Control for NycoCard HbA1c

**Device common or usual name or classification name:**

Glycosylated Hemoglobin Control

PRODUCT NOMENCLATURE	CLASSIFICATION NUMBER	CLASS	PANEL
Control, Single Analyte (Assayed or Unassayed)	862.1660 (JJX)	I	Chemistry

### I. Substantial Equivalence

**HbA1c Control for Axis-Shield NycoCard** is substantially equivalent in function, safety and efficacy to Primus Liquid Control for GHb/A1c [K992921].

#### Comparison of Technological Characteristics with Predicate Device

Characteristic	New Device	Predicate Device
Name:	RNA1c Control for NycoCard HbA1c	Primus Liquid Control for GHb/A1c
510(k), Date:		K992921, 11/12/1999
Description:	Glycosylated bovine hemoglobin hemolysate with polystyrene beads to simulate blood cells.	Liquid, whole blood hemolysate prepared from diabetic and non-diabetic whole bloods.
Intended Use:	As a quality control solution for use to verify the performance of the Axis-Shield NycoCard reader for the measurement of HbA1c	As a quality control solution for use to verify the performance of the Axis-Shield NycoCard reader for the measurement of HbA1c
Number of levels:	2	2
Analytes:	Glycated hemoglobin (HbA1c%)	Glycated hemoglobin (HbA1c%)
Container:	3 mL clear glass vial with plastic cap	1 mL clear glass vial with plastic cap.

<sup>1</sup> This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Characteristic	New Device	Predicate Device
Serology Testing of Human Source Material	No serology testing is necessary. Non-human source material	Non-reactive for: <ul style="list-style-type: none"> <li>• Hepatitis B Surface Antigen</li> <li>• Antibody to Hepatitis C</li> <li>• Antibody to HIV</li> </ul>
Storage:	2 - 8 C, or -20 C	2 - 8 C
Stability of unopened Product:	12 months at 2 - 8 C	9 months at 2 - 8 C
Stability of opened Product:	30 days at 2 - 8 C	30 days at 2 - 8 C
Color:	Red	Dark red

## II. Description of the new device

Glycosylated Hemoglobin (HbA1c) is a human hemoglobin A (HbA0) with glucose irreversibly bound to the N-terminal valine of the beta-chain. %HbA1c is the percentage of glycosylated hemoglobin molecules as a percentage of the total hemoglobin concentration.

%HbA1c is quantified on medical devices by turbidimetric inhibition immunoassay (TINIA), ion-exchange HPLC, boronate affinity HPLC or gel electrophoresis.

The Axis-Shield NycoCard reader[K993131] determines HbA1c concentration by the boronate affinity test principle and hemoglobin concentration photometrically. Using the values obtained for each of these two analytes, the percentage of the total hemoglobin that is glycated is calculated and reported as HbA1c%.

**RNA1c** Control for NycoCard HbA1c is a two-level, glycated bovine hemoglobin liquid control solution with dyed polystyrene beads to provide the appropriate total hemoglobin value. The concentration of dyed beads and glycated hemoglobin are optimized for the Axis-Shield NycoCard reader to provide measurement values for HbA1c equivalent to the predicate device, Primus Liquid Control for GHb/A1c.

**RNA1c** Control for NycoCard HbA1c provides a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC material as a part of their quality assurance program. The product is packaged in a glass bottle.

**RNA1c** Control for NycoCard HbA1c is a minimally hazardous liquid control solution containing no human biological materials and requires no reconstitution prior to use.

(5) **Intended use of the device**

**RNA1c** Control for NycoCard HbA1c is intended for use to verify the performance of the Axis-Shield NycoCard HbA1c reader with normal and elevated glycosylated hemoglobin levels within the reportable range.

(6) **Technological characteristics of the device.**

**RNA1c** Control for NycoCard HbA1c is a two-level, glyated bovine hemoglobin liquid control solution with dyed polystyrene beads to provide the appropriate total hemoglobin value. The concentration of dyed beads and glyated hemoglobin are optimized for the Axis-Shield NycoCard reader to provide measurement values for HbA1c equivalent to the predicate device, Primus Liquid Control for A1c/GHb.

(b) (1) **Summary of non-clinical tests submitted with the premarket notification for the device.**

Tests were conducted to verify specific performance requirements:

- a) Closed bottle stability
- b) Stability after opening
- c) Correlation to predicate device
- d) Test precision and range

(b) (2) **Summary of clinical tests submitted with the premarket notification for the device.**

N/A

(b) (3) **Conclusions drawn from the clinical and non-clinical trials.**

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 13 2005

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Kathleen Storro  
Director, QA and Regulatory Affairs  
Bionostics, Inc.  
7 Jackson Road  
Devens, MA 01434

Re: k050961  
Trade/Device Name: **RNA/c** Control for NycoCard HbA1c  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality control material (assayed and unassayed)  
Regulatory Class: Class I  
Product Code: JJX  
Dated: April 15, 2005  
Received: April 18, 2005

Dear Ms. Storro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

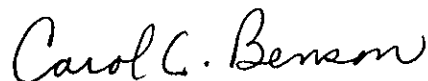
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Carol C. Benson". The signature is written in a cursive, flowing style.

Carol C. Benson, M.A.  
Acting Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K050961

Device Name: **RNA1c Control for NycoCard HbA1c**

Indications For Use:

**RNA1c** Control for NycoCard HbA1c is intended to be used to monitor and evaluate the analytical performance of the Axis-Shield NycoCard HbA1c reader for the measurement of glycosylated hemoglobin. The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practice. The two levels of controls allow performance monitoring within the clinically important range.

For *In Vitro* Diagnostic Use

Prescription Use   ✓    
(Part 21 CFR 801 Subpart D)

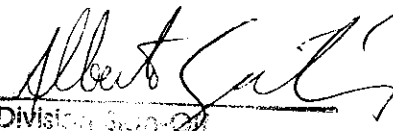
AND/OR

Over-The-Counter Use         
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division Sign-off

Office of In Vitro Diagnostic  
Devices Evaluation and Safety

510(k) K050961

Page 1 of   1